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Safety and Efficacy of Overlapping Second Generation Drug-Eluting Stents Based Upon 2-year Clinical outcomes. Results from the Pooled Analysis of Five Trials from the International Global RESOLUTE Program.

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Background: Overlapping first generation drug eluting stents (DES) have been demonstrated in preclinical models to show evidence of a persistent inflammatory response, fibrin deposition and delayed endothelialisation. The SIRTAX (Sirolimus-Eluting Versus Paclitaxel-Eluting Stents for Coronary Revascularization) Trial (n=1012) associated the implantation of overlapping first generation DES with impaired angiographic and adverse 3-year clinical outcomes, including death or myocardial infarction (MI).
Methods: Patient level data from 5 controlled studies of the RESOLUTE Global Clinical Program evaluating the RESOLUTE zotarolimus-eluting stent (R-ZES) were pooled (n=5130). Enrolment criteria encompassed more complex patients, including acute MI, long lesions, unprotected left main, bifurcations, total occlusions, bypass grafts & visible thrombus. The position of the R-ZES in relation to the previous implanted stents during the index or staged procedures were reported by the study site as either 'separate,' 'abutting' or 'overlapping.' Comparisons of clinical outcomes – using propensity score adjustment of baseline anatomical and clinical characteristics – were undertaken between patients implanted with at least one overlapping DES against patients with no overlapping DES (Kaplan Meier analyses).
Results: 644 of 5130 study patients (12.6%) underwent overlapping DES implantation. Baseline characteristics indicated that the implantation of overlapping DES compared to non-overlapping DES (n=4486) were performed more frequently in the RCA and in more complex coronary lesions. Thirty day, 1 & 2 year clinical outcomes indicated comparable all-cause death (2 year overlap vs. non overlap: 5.1% vs. 3.5%, p=0.13), cardiac death (3.0% vs. 2.1%, p=0.36), MACE (13.3% vs. 10.7%, p=0.19), target lesion (10.9% vs. 9.0%, p=0.41) & target vessel (12.8% vs. 10.6%, p=0.25) failure, and stent thrombosis (ARC definite/probable 1.4% vs. 0.9%, p=0.16).
Conclusions: The adverse clinical outcomes associated with 1st generation DES were not apparent with 2nd generation DES. Overlapping second generation DES (compared to the non overlap) is safe & effective with comparable 2 year clinical outcomes, including repeat revascularisation.

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Impact of the New BioMime™ Sirolimus-Eluting Stent in Comlex Patients of Daily Practice – Preliminary Results of the MeriT-2 Study

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Background: The new drug-eluting stent BioMime™ (Meril Life Sciences Pvt. Ltd., Gujarat, India) is composed of an ultra-thin platform (strut thickness 0.0026'') , a biodegradable polymer and sirolimus. Its clinical efficacy and safety had already been demonstrated. However, the impact of the BioMime™ SES on populations from daily practice with complex lesions is not fully determined.
Methods: The meriT-2 was a prospective, non-randomized, multicenter study, with minimally selected patients and evaluated clinical and safety performance of the BioMime™ SES in the treatment of complex patients from daily practice. Native coronary lesions ranging from 2.5-3.5 mm in diameter and with ≤37 mm in length, and chronic total occlusions were included. Lesions located at the left main coronary or in saphenous vein grafts, or patients with acute myocardial infarction (MI) or left ventricular ejection fraction <30% were excluded. Clinical follow-up (FU) was performed in 1, 8 and 12 months; angiographic FU at 8 months. The primary outcomes were major adverse cardiac events (MACE: death, MI and target-lesion revascularization –TLR) in 1 month, and late lumen loss (LLL) in 8 months.
Results: A total of 242 patients were included. Mean age was 56.7 years, 37% diabetics, 32% had previous MI, most with type B2/C lesions, 40% with multiarterial disease and 52% presenting in acute coronary syndrome. Medians of lesion length, reference diameter and % stentosis were: 15.8mm [13.47-21.42], 2.79mm [2.42-2.99], and 89.8 [83.2-93.2], respectively. A total of 363 stents were implanted. There were no MACE afer 30 days and the LLL in 8 months (n=132) was 0.15 mm [0.09-0.33]. Cumulative rates of MACE in 12 months were 5.7% (0.5% cardiac death; 4.7% TLR). There were 3 cases of stent thrombosis (ST) - 1 acute, 1 sub-acute and 1 late.
Conclusions: In this multicenter evaluation of complex "real-world" patients, the new BioMime™ SES has shown excellent efficacy and safety, with low rates of MACE and ST in 1 year, as well as low values of LLL.

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Feasibility and clinical outcomes of ≥38 mm long drug eluting stent treatment for diffuse coronary artery disease in Egyptian population

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Background: Diffuse long lesions are commonly encountered in routine clinical practice and often lead to use long or overlapping stents. Limited data are available on the long-term efficacy and safety of long drug-eluting stents (DES) in this complex lesion subset. We investigated the long-term efficacy and safety of ≥38mm-long DES in patients undergoing stent implantation for de novo diffuse long lesions.
Methods: 129 consecutive patients who underwent coronary artery stenting with ≥38mm-long DES in real world practice were included. Study endpoints were major adverse cardiac events including cardiac death, myocardial infarction, repeat revascularization and stent thrombosis.
Results: 129 pts with 153 lesions were enrolled, 85.2% were male, mean age 58.2±10 yrs. Lesions were treated with at least one 38mm second generation DES, all post-dilated at high atmosphere (>20 atm) with NC balloons. Mean stent size was 3.0±0.2 mm, mean stent length was 54.5 mm. Two-year clinical outcomes were compared between diabetic (DM) (n =40) and non-DM patients (n =89). Baseline characteristics were similar in the two groups as were mean stent length (50.2 ± 13.1 mm in DM and 54.5 ± 15.7 in non-DM, p = 0.12). Mean follow-up duration was 433±275 days, and 2-yr cumulative major adverse cardiac events were significantly lower in the non-DM than in DM group (5.6% in non-DM vs 10% in DM, p = 0.03). Clinically driven TLR was 5.4% and no cardiac death was reported. There was 1 case defined as late stent thrombosis. The independent predictors of repeat revascularization were insulin treated type 2 diabetes mellitus, reference vessel diameter (RVD) <2.75 mm and the use of overlapping DES longer than 60 mm.
Conclusions: The use of ≥38mm DES for treatment of complex diffuse disease is safe and effective with an acceptably low 2-year MACE rate. The need for repeat revascularization was increased with overlapping long DES, small RVD, and insulin treated DM patients.

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A Comparison of Drug Eluting Stents in a Bench Artery Dissection Model

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Background: Dissections during stenting are rare but can lead to clinical complications and necessitate use of a secondary stent thus increasing direct cost of the procedure. This study examined four popular DES products (Resolute Integrity-Medtronic; Xience Prime and Xience V-Abbott; and Promus Element-Boston Scientific) using a bench model developed to explore factors that contribute to dissections.
Methods: Devices (n=5) were inserted into mock vessels designed to match the compliance of a native artery and inflated from nominal to 20-atm pressure. Inner diameters and outward pressures against the vessel wall were ascertained at 500-μm increments at each inflation pressure. Desired forces within stent body were compared to undesired forces associated with balloon transition and overhang.
Results: Resolute Integrity and Promus Element exerted consistent pressures within the device body and decreasing forces in the distal balloon overhang regions. Xience devices flared as they approached the distal transition, and highest vessel stretch was observed in the balloon overhang. This flaring or "trumpeting" phenomenon was not observed in other DES.

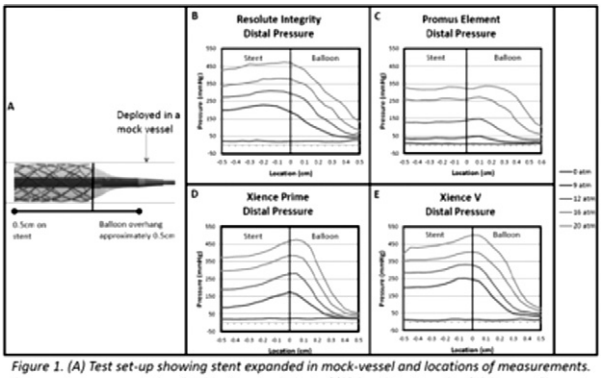

Figure 1. (A) Test set-up showing stent expanded in mock-vessel and locations of measurements. Pressure curves across the distal balloon and stent of (B) Resolute Integrity, (C) Promus Element, (D) Xience Prime, and (E) Xience V. The stent is on the left half of the graph (-0.5-0cm) and the balloon is on the right (0-0.5/0.6cm). Measurements were recorded at the corresponding inflation pressures.

Conclusions: This "trumpeting" may also partially explain the observed use of more Xience stents per lesion compared to Resolute (1.18±0.45 vs. 1.15±0.42, p=0.02) in the Resolute All Comers (RAC) trial. The primary cause for secondary stenting in RAC was "to stabilize target lesion" which includes procedural complications including dissection or perforations.

TCT-653

Assessment of endothelial function in patients randomly treated with a polymer-free sirolimus eluting stent and its bare-metal equivalent: results of the VESTASYNC II trial

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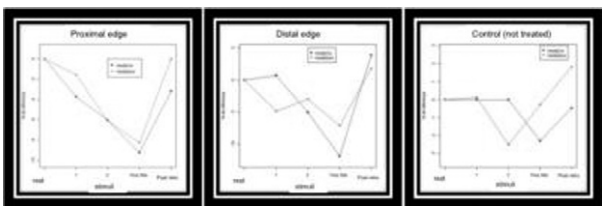
Background: Endothelium dysfunction is among the possible causes related to higher thrombosis rates after 1st generation DES. Whether the presence of durable polymer or high anti-proliferative drug dose, or both, can be responsible for this phenomenon is not clear. In the present study we compared the endothelial function following the implant of a polymer-free DES with a nanothin-microporous hydroxyapatite surface coating impregnated with a low-dose of Sirolimus (55μg) to a BMS equivalent coated with a hydroxyapatite surface (Vestacor stent).
Methods: The Vestasync II is a randomized, double-blinded trial with 20 pts (10 in each group) with de novo lesions in native coronary arteries of 3.0-3.5mm diameter and ≤ 14mm in length. The primary goal was to compare the vasomotricity after implantation of stents with the same platform, with and without drug elution. Endothelial function was assessed with atrial pacemaker stimulation (20 ppm over basal cardiac frequency until reach 150 ppm) and the lumen diameter was measured at 5 mm of proximal and distal stent edges and in a control segment, in different stages (at rest, at successive phases of stimulli and after nitroglycerin I.C infusion).
Results: As shown in the figure, there was a negative variation in luminal diameter between basal and maximum stimulli at proximal (10%) and distal (8%) edges of both groups. Among control segments this variation was less than 3%, an acceptable variation of QCA method.



Conclusions: The elution of sirolimus does not seem to interfere in endotelial function 8 months after polymer-free hydroxiapatite coating stent implantation.

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Comparison in the 5-year Outcome of Pericardium and Polytetrafluoroethylene-Covered Stents for Saphenous Vein Graft Lesions

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Background: Percutaneous intervention (PCI) for degenerated saphenous vein graft (SVG) lesions are well known for high rates of no-reflow, restenosis (ISR) and stent thrombosis. Covered stents have been tried in an aim to trap the debris to minimize no-reflow and ISR. Two types of covered stents have been used for SVG lesions: pericardium covered stent (PCS) & polytetrafluroethylene (PTFE) covered stent. We present our long-term follow-up data following the use of both types of covered stents in our practice.
Methods: Between 1997 and 2004, 52 patients (mean age: 67.14 years) with 65 lesions in SVG were treated with PTFE covered stents as a part of multicenter trial (RECOVERS). Between 2003 and 2007, 33 patients (mean age: 67.78 years) with 48 SVG lesions were treated with pericardium-covered stents covered stents as a part of multicenter trial (SLEEVE II).
Results: All case had TIMI3 flow post PCI and there were no immediate post-procedural complications. There were no significant differences in the baseline characteristics except that mean length of PCS were significantly longer than PTFE covered stents (32.3 mm vs 25.1 mm, p<0.001). At 5-year follow-up, the rates of TLR was [PTFE: 12 (18.5%), PCS: 13 (27%) p=0.17], TVR was [PTFE: 14 (21.5%), PCS: 16 (33%) p=0.07]. During the 5-year follow-up period, 8 patients (15%) in the PTFE group and 2 patients (6%) in the PCS group had died; p=0.33. The MACE defined as death, MI, clinically driven TVR occurred in 34 of 52 PTFE patients (63%) vs. 18 of 33 PCS patients (54.5%); p=0.2. There were two reported cases of definite very late stent thrombosis in the PCS group, but none in the PTFE group.
Conclusions: The 5 year follow-up data shows no significant differences in the clinical endpoints between the two covered stents, although numerically it was slightly worse in the PCS group. The rates of TLR and TVR are not discouraging in either stents given the complexity of SVG lesions. Considering the complexity of the lesions treated and the absence of no-reflow, covered stents may provide additional protection. Since there are no very long-term follow-up with other stents in SVG, we cannot compare these results with the traditional stents.

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Outcomes of high-risk patients undergoing percutaneous coronary interventions in the ambulatory versus in-hospital setting

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Background: In this study, we investigated the safety of ambulatory percutaneous coronary intervention (PCI) in high-risk patients according to age, creatinine, ejection fraction (ACEF) scores.
Methods: The ambulatory PCI group consisted of all consecutive PCI with same-day discharges at Mount Sinai Hospital from January 1, 2003 to March 31, 2011 who had follow-up data. The overnight group consisted of all PCI outpatients in 2004 who were then hospitalized for at least one night. Patients were stratified into two groups based on ACEF score: low (<1.100) and high (≥1.100). The primary endpoint was a 30-day major adverse cardiac events (MACE: readmission, all-cause death, and myocardial infarction (MI).
Results: Out of 4932 patients, 3216 or 65.2% were in the ambulatory group and the rest (1716) were in the control group. The average age was 61.5 years and were no significant differences in baseline characteristics. Overall 30-day MACE occurred in similar frequency in both groups (Table), in high and low ACEF scores.

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